

Rejoinder

Claims 14-19 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 1-13, 52, and 57-60, directed to the process of making or using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 20-50, directed to the inventions of a granular bone substitute material and a method of fabricating the granular bone substitute material, do not require all the limitations of an allowable product claim, and have NOT been rejoined.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement between groups I, II and VI as set forth in the Office action mailed on February 4, 2009 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Amy Dunstan, Ph.D. on April 11, 2011.

The claims:

1. (Currently amended) A method of fabricating a bone substitute material, the method comprising the steps of:

providing a foam material having an open cell structure,
distorting the shape of the foam material and holding the material in a distorted shape,
coating the walls of the cells of the foam material with a ceramic slip,
removing the foam material, and

sintering the ceramic slip to form a bone substitute material ~~that is approximately a positive image of the distorted foam material~~, wherein the bone substitute material comprises a porous sintered ceramic, the porous sintered ceramic being composed from hydroxyapatite or tricalcium phosphate, and the porous sintered ceramic having approximately the form of a positive image of an open celled foam material, the walls defining the cells within the material being hollow such that each wall defining cells has two wall ceramic material layers and a hollow cavity extending between the two wall ceramic material layers, wherein the cellular structure is orientated such that the cells are elongated, having generally have a length in one direction greater than a length in a perpendicular direction a length in one direction greater than their lengths in the two other perpendicular directions and wherein the bone substitute material has a breaking stress of more than 1 MPa.

14. (Currently Amended) A bone substitute material comprising a porous sintered ceramic, the porous sintered ceramic being composed from ~~one or more suitable bone substitute ceramics, such as~~ hydroxyapatite or tricalcium phosphate, and the porous sintered ceramic having approximately the form of a positive image of an open celled foam material, the walls defining the cells within the material being hollow such that each wall defining cells has two wall ceramic material layers and a hollow cavity extending between the two wall ceramic material layers, wherein the cellular structure is orientated such that the cells are elongated, having generally have a length in one direction greater than a length in a perpendicular direction a length in one direction greater than their lengths in the two other perpendicular directions and wherein the bone substitute material has a breaking stress of more than 1 MPa.

16. (Currently Amended) A bone substitute material according to claim ~~15~~ 14, in which the cells have a length in one direction more than 20% greater than their length in the two other perpendicular directions.

52. (Currently amended) A method of forming a bone graft comprising the steps of implanting a bone substitute material ~~that is approximately in the form of a positive image of an open celled foam material~~ into or onto a bone, wherein the bone substitute material comprises a porous sintered ceramic, the porous sintered ceramic being composed from hydroxyapatite or tricalcium phosphate, and the porous sintered ceramic having approximately the form of a positive image of an open celled foam material, the walls defining the cells within the material being hollow such that each wall defining cells has two wall ceramic material layers and a hollow cavity extending between the two wall ceramic material layers, wherein the cellular structure is orientated such that the cells are elongated, having generally have a length in one direction greater than a length in a perpendicular direction their lengths in the two other perpendicular directions and wherein the bone substitute material has a breaking stress of more than 1 MPa.

Cancel claims 15 and 19-50.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: Note that support for the walls defining the cells within the material being hollow such that each wall defining cells has two wall ceramic material layers and a hollow cavity extending between the two wall ceramic material layers can be found at description at second full paragraph in page 2 of the specification of the present invention. The 112 rejections have been overcome in view of the present amendment.

Of the references of record, the most pertinent are EP 254 557, Zhang et al. (US 2005/0158535) and Twigg et al. (US 4,810,685).

EP'557 teaches a filter of a porous sintered ceramic body having approximately the form of a positive image of an open celled foam material (example 1). Since EP'557 uses the same approach as disclosed in the present invention to form the porous sintered ceramic body, the walls defining the cells within the material will be inherently hollow due to removal of the foam material during sintering. The foam cells are elongated with the ratio of the average major axis to the average minor axis of 1.9 (example 1). The ceramic body is made from alumina, silica, silicone carbide. There is no motivation and guidance to modify the filter of EP'557 by incorporation of hydroxyapatite or tricalcium phosphate therein to arrive at the claimed invention.

Zhang teaches a bone substitute material of a porous sintered ceramic body having approximately the form of a positive image of an open celled foam material (paragraphs 62 and 63). The bone substitute material is made from hydroxyapatite or

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tricalcium phosphate. Zhang does not specifically disclose the foam pores being oriented in a manner such that the foam pores are elongated, having a length in one direction greater than a length in a perpendicular direction. Zhang has only one line of description of “porous ceramic structure of the invention can be used as filter” (see paragraph 12 of the specification of the present invention), but Zhang does not disclose anything at all that the filter means the air filter used in the vehicles for purifying exhaust gas by removing harmful gas components such as carbon monoxide, nitrogen oxide in exhaust gas. In addition, Zhang discloses the pore size in the range from 100 to 300 microns, which is completely outside the range of 500 to 7000 microns disclosed in EP' 557. The articles in both references are made from completely different materials, i.e. hydroxyapatite vs. silica, and serve different purposes, bone substitute vs. air filter. Therefore, one skilled in the art would not be motivated to have the foam pores of Zhang oriented in a manner as taught by EP'557 because Zhang does not disclose anything at all that the filter means the air filter for vehicles. Accordingly, the combination of Zhang and EP'557 are improper due to their differences in pore size, materials and purposes.

Twigg discloses a filter comprising a ceramic foam having approximately the form of a positive image of an open celled foam material by impregnation of the foam material with a ceramic slurry, followed by drying and firing the impregnated foam to remove the foam material and to cause the ceramic material to sinter (abstract). The ceramic material includes silica, alumina and silicon carbide. There is no motivation to

modify the filter of Twigg by incorporation of hydroxyapatite or tricalcium phosphate therein to arrive at the claimed invention.

Note that, none of the prior art references, taken individually or in combination, teach or suggest the bone substitute material having a recited structure set out in the claim. Accordingly, the instant claims are deemed allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-1485. The examiner can normally be reached on Monday through Thursday, from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alicia Chevalier can be reached on (571) 272-1490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Hai Vo/
Primary Examiner, Art Unit 1788